



FOR IMMEDIATE RELEASE

Exosome Diagnostics Presents Data Demonstrating Ability to Detect EML4-ALK Fusion Transcripts on Exosomal RNA in Patients with Non-Small Cell Lung Cancer

Plasma-based assay detects EML4-ALK mutation, specific associated fusion variants; Holds potential to help more precisely match patients with targeted therapies

Company plans to launch EML4-ALK liquid biopsy test in second half of 2015

CAMBRIDGE, Mass., April 20, 2015 – Exosome Diagnostics, Inc., a developer of revolutionary, biofluid-based molecular diagnostics, today announced data demonstrating the ability to detect the EML4-ALK mutation and specific associated RNA fusion transcripts in blood plasma of patients with non-small cell lung cancer (NSCLC). The data were presented at a [poster session](#) yesterday, Sunday, April 19, 2015, titled, “Plasma-based diagnostics for detection of EML4-ALK fusion transcripts in NSCLC patients,” at the American Association for Cancer Research (AACR) Annual Meeting in Philadelphia, Pa.

Currently undergoing clinical validation, the company’s novel EML4-ALK liquid biopsy test is designed to isolate and analyze exosomal RNA (exoRNA) from a blood sample to detect EML4-ALK fusion transcripts, with the goal of informing more individualized treatment decisions for patients.

“We’re very encouraged by these data and believe our EML4-ALK liquid biopsy test, with its unique ability to analyze RNA from plasma, can address the significant need for more sensitive, accurate EML4-ALK detection,” said [Vince O’Neill, M.D., Chief Medical Officer](#) at Exosome Diagnostics. “There are many known fusions of the ALK gene; we believe our assay’s demonstrated ability to differentiate which fusion is present will help guide more precise, personalized treatment selection for patients.”

In the study, the Exosome Diagnostics EML4-ALK assay detected all EML4-ALK fusion transcripts based on the presence of the ALK kinase domain; importantly for therapy selection, the assay was able to differentiate between the three major known fusion transcript variants, which represent the vast majority of all EML4-ALK-positive cases. The assay displayed high selectivity over wild type background, and data showed correlation with tissue-based analysis (FISH). Additionally, unlike using circulating tumor cells (CTCs) for liquid biopsy, this test can be performed on either fresh or frozen plasma, and does not require special shipping or storage provisions.

Patients with NSCLC in whom the EML4-ALK mutation is accurately detected can be matched to treatment with approved ALK kinase inhibitors. In addition, there are several other therapies in clinical development currently being evaluated to target this mutation. Exosome Diagnostics’ EML4-ALK liquid biopsy test is designed to be a complement to tissue biopsy or an alternative when proceeding with a tissue biopsy is not desirable or possible. Requiring only a blood draw, the test helps overcome certain

challenges associated with tissue biopsies and fine-needle aspirates, including potential surgical complications, availability of tissue, and tissue sample heterogeneity, which can lead to mutations going undetected. Upon completion of further validation studies, Exosome Diagnostics plans to begin making the EML4-ALK liquid biopsy test available to physicians in the second half of 2015.

Exosome Diagnostics' [Chief Scientific Officer, Johan Skog, Ph.D.](#), will give a separate oral presentation tomorrow, Tuesday, April 21, 2015, at the AACR Meeting titled, "Exosomes: Next-generation diagnostics," as part of the [Major Symposium: Liquid Biopsy Approaches for Detecting, Monitoring, and Characterizing Human Cancer](#). This symposium will be held from 1:00 – 3:00 p.m. ET in the Terrace Ballroom II-III (400 Level) at the Pennsylvania Convention Center.

About the Technology

Exosome Diagnostics' EML4-ALK liquid biopsy test utilizes the company's [proprietary, patented exosome-based technology](#) to detect the presence of the mutation and specific associated fusions. Exosomes are messengers released by all living cells into biofluids, such as plasma/serum, urine, cerebrospinal fluid and saliva. Exosomes contain RNA, DNA and proteins from their cell of origin. Exosome Diagnostics' technology platform can achieve real-time access to comprehensive molecular information about cells in the body without direct access to the actual cells. The company's platform is uniquely versatile, enabling the development of tests that can analyze either exosomal RNA (exoRNA) alone or, when appropriate, simultaneously isolate and analyze exoRNA and cell-free DNA (cfDNA).

In addition to the EML4-ALK liquid biopsy test, Exosome Diagnostics also plans to launch liquid biopsy tests for the T790M resistance mutation in lung cancer, as well as for prostate cancer and other solid tumor cancers in the second half of 2015.

About Exosome Diagnostics

Exosome Diagnostics is a privately held company focused on developing and commercializing revolutionary biofluid-based diagnostics to deliver personalized precision healthcare that improves lives. The company's novel exosome-based technology platform can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are detected, diagnosed, treated and monitored. Visit www.exosomedx.com to learn more.

Company Contact:

Hannah Mamuszka, MS
Vice President Business Development
Exosome Diagnostics
hannah@exosomedx.com

Media Contact:

Feinstein Kean Healthcare
Meghan Weber
P: +1-617-761-6712
M: +1-781-479-7362
meghan.weber@fkhealth.com